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Docket No: 4016.3004 US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Francis Louisa Titus, Jeffrey C. Marx, Scott D. Boden,
Sangwook T. (Tim) Yoon, and Susan Drapeau

Application No.: 10/806,915 Group: 1632

Filed: March 23, 2004 Examiner: Qian, Celine X.

Confirmation No.: 4427

For: INTRACELLULAR DELIVERY OF OSTEOINDUCTIVE PROTEINS
AND PEPTIDES

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INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
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Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application
filewrapper. (Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

(Applies to original applications (other than design) filed on or after May 29, 2000)

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in -§ 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references (AI-AV2) are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.
[The earlier application contains copies of the cited references.]
- ☒ The listed references (AR-AS) were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account ☐ in the amount of [\$]. A copy of this Statement is enclosed.
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Respectfully submitted,

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ATTORNEY DOCKET NO.

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APPLICATION NO.

10/806,915

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

July 18, 2005

(Use several sheets if necessary)

FIRST NAMED APPLICANT

Francis Louisa Titus

FILING DATE

March 23, 2004

CONFIRMATION NO.

4427

GROUP

1632

U.S. COPENDING APPLICATIONS

[illegible]

EXAMINER

DATE CONSIDERED

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Fujiyama, S., <i>et al.</i> , "Inhibition of NF- κ B by a Cell Permeable Form of 1 κ Ba induces apoptosis in eosinophils, <i>BBRC</i> , 326:632-637 (2005).
AS	Porter, T., <i>et al.</i> , "Biomolecules in Tissue Engineered Medical Products (TEMPs): A Case Study of Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2), <i>Journal of ASTM International</i> , January 2004, 1(1):1-21.
AT	Boden, <i>et al.</i> , "Adenoviral Delivery of LMP-1 Induces Consistent Spine Fusion," 47 th Annual Meeting, <i>Orthopaedic Research Society</i> , San Francisco, California (2001)
AU	Nagahara, <i>et al.</i> , "Transduction of full-length TAT fusion proteins into mammalian Cells: TAT-p27 ^{Kip1} Induces Cell Migration, <i>Nature Medicine</i> , 4(12):1449-1452 (1998)
AV	Southern, <i>et al.</i> , "Detection of Specific Sequences Among DNA Fragments Separated by Gel Electrophoresis," <i>J. Mol. Biol.</i> , 98:503-517 (1975)
AW	Alwine, <i>et al.</i> , "Detection of Specific RNAs or Specific Fragments of DNA by Fractionation in Gels and Transfer to Diazobenzyloxymethyl Paper," <i>Meth. Enzymol.</i> , 68:220-242 (1979)
AX	Sambrook, <i>et al.</i> , "Extraction of RNA with Guanidinium Thiocyanate Followed by Centrifugation in Cesium Chloride Solutions," <i>Molecular Cloning: A Laboratory Manual</i> , 2 nd ed., <i>Cold Spring Harbor Press</i> , 7.19-7.50 (1989)
AY	Heldin, <i>et al.</i> , "TGF- β Signalling from Cell Membrane to Nucleus through SMAD Proteins," <i>Nature</i> , 390:465-471 (1997)
AZ	Lin, <i>et al.</i> , "Inhibition of Nuclear Translocation of Transcription Factor NF- κ B by a Synthetic Peptide Containing a Cell Membrane-permeable Motif and Nuclear Localization Sequence," <i>J. Biol. Chem.</i> , 270(24):14255-14258 (1995)
AR2	Rojas, <i>et al.</i> , "Genetic engineering of proteins with membrane permeability," <i>Nat. Biotech.</i> , 16:370-375 (1998)
AS2	Fawell <i>et al.</i> , "Tat-mediated delivery of heterologous proteins into cells," <i>Proc. Natl. Acad. Sci. USA</i> , 91:664-668 (1994)
AT2	Schwarze, <i>et al.</i> , "Protein Transduction: Unrestricted Delivery into all Cells," <i>Trends in Cell Biology</i> , 10:290-305 (2000)
AU2	Jiang, <i>et al.</i> , "Pluripotency of Mesenchymal Stem Cells Derived from Adult Marrow," <i>Nature</i> , 418:41-49 (2002)
AV2	Viggeswarapu, <i>et al.</i> , "Adenoviral Delivery of LIM Mineralization Protein-1 Induces New-Bone Formation <i>In Vitro</i> and <i>In Vivo</i> ," <i>J. Bone Joint Surg.</i> , 83(3):364-376 (2001)

EXAMINER

DATE CONSIDERED